UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD RICE, AS TRUSTEE OF THE RICHARD E. AND MELINDA RICE REVOCABLE FAMILY TRUST 5/9/90, and CHRISTIAN STANKEVITZ, Individually and On Behalf of All Others Similarly Situated,	:	21-cv-00036 (LJL)
Plaintiff,	:	ORAL ARGUMENT REQUESTED
v.	:	
INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI, and SANDIP S. KAPADIA,	:	
Defendants.	:	

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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1. ***Plaintiffs Have Abandoned Their Core Fraud Theory In Light Of Documents Showing Their Allegations Lack Factual Bases.*** Plaintiffs criticize Defendants for attaching publicly-available SEC documents, investor call transcripts and FDA materials to their motion that are either referenced, incorporated in or integral to the FAC. (Opp. at 2.) Those documents—the authenticity or reliability of which are not disputed—demonstrate that Plaintiffs' core allegations of fraud are meritless, contradict the allegations and appear to have been made without reasonable inquiry. In particular, Ocaliva's FDA-approved label directly contradicts Plaintiffs' theory that Defendants became aware of but intentionally or recklessly failed to disclose certain SAEs that were not listed on Ocaliva's label. (*See* Defendants' Moving Brief (ECF No. 68) ("Mov. Br.") at 16-17; Musoff Decl. Ex. 7; FAC ¶¶ 35, 43.) That Ocaliva label shows that three of the five types of alleged SAEs (*i.e.*, chronic hepatic failure, hepatic failure and portal hypertension)—which account for 85% of the cases listed on Plaintiffs' SAE table as "Not labelled"—were in fact listed on the label. (Mov. Br. at 16-17; Musoff Decl. Ex. 7.)

In a tacit admission that those allegations can no longer form the basis for their claim, Plaintiffs relegate their response to a single footnote in their Opposition brief, characterizing Defendants' argument about how many SAEs were included on the label as a "quibble." (Opp. at 21 n.13.) But the thrust of Plaintiffs' FAC is that Defendants failed to disclose those purportedly "Not labelled" SAEs and that those "Not labelled" SAEs presented an undisclosed material risk to the NASH NDA. (FAC ¶¶ 5, 42-44.) Plaintiffs repeat this allegation in their FAC as the only alleged reason why many of the challenged statements were allegedly misleading. (FAC ¶¶ 81, 88, 90, 96.) The Court should reject Plaintiffs' attempt to blind the Court from these contradictory facts that demonstrate the falsity of Plaintiffs' allegations. *In re*

Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 555 (S.D.N.Y. 2004) ("The court need not accept as true an allegation that is contradicted by documents on which the complaint relies.").[1]

2. *Plaintiffs Fail To Allege A Strong Inference of Scienter Because Defendants Had No Duty To Disclose The SAEs To Investors.*[2] The Opposition concedes that *Matrixx* provides the governing standard for determining whether a complaint has adequately pleaded a duty to disclose SAEs to investors. (Opp. at 19 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011).) *Matrixx* held that "something more" than the "mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—" is needed to demonstrate a "reliable causal link" and establish a duty to disclose. 563 U.S. at 44-45.

Plaintiffs attempt to plead the "something more" by pointing to unvalidated statistical evidence in the form of "risk odds ratio" scores that were plucked from a *post-Class Period* news article and generated by a software vendor not used by the FDA to conduct such statistical analyses. (Mov. Br. at 15.) And the Opposition now makes a halfhearted attempt to buttress that vendor's analysis, arguing that it should be credited over Defendants' "ad hoc" analysis because the vendor was "unbiased" and the results showed "staggering" ROR scores. (Opp. at 20-21.) Yet even accepting that vendor's ROR scores *as true*, Plaintiffs still failed to plead the requisite

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[1] The Opposition does not cure Plaintiffs' deficient allegations that Defendants' opinion statements and accurate risk factor disclosures are actionable or that Defendants made omissions about publicly-available SAEs accessible on FAERS. (Opp. at 22-24; Mov. Br. at 29-34.)

[2] Plaintiffs assert that their omission allegations should be analyzed under a plausibility standard because Defendants couch their scienter arguments as a failure to allege materiality and a duty to disclose. (Opp. at 26 n.15.) That is wrong. Where, as here, a plaintiff asserts a scienter theory based on material omissions, a strong inference of scienter cannot be inferred without particularized allegations demonstrating a "clear duty to disclose." *Kalnit v. Eichler*, 264 F.3d 131, 143-44 (2d Cir. 2001); (Mov. Br. at 10.) Plaintiffs fail to meet their burden.

"something more": at most, the RORs generated a hypothesis about a potential safety signal that could not be used in isolation to establish causality. (Mov. Br. at 14.) This is particularly true where the ROR scores identified several liver-related SAEs that are known to be associated with the progression of PBC itself and therefore can be confounding factors. (Mov. Br. at 15.) Plaintiffs also do not allege that Defendants were aware of any of those ROR scores during the alleged Class Period. (*Id.*)

Plaintiffs next attempt to plead "something more" by claiming that the SAEs "reflected the long-term impact of OCA in PBC patients" in contrast to the 18-month study period for the noncirrhotic NASH NDA. (Opp. at 21.) But nowhere do Plaintiffs allege any particularized facts showing how long any given patient who had experienced an SAE was exposed to Ocaliva. Plaintiffs instead guess that the SAEs occurred in PBC patients who "potentially" took Ocaliva for "longer than 18 months, even multiple years." (FAC ¶ 51.) In any event, the purported long-term impact of Ocaliva "as reflected by SAEs" (Opp. at 19) has no import under *Matrixx*: the mere existence of SAE reports, standing alone, says nothing about whether Ocaliva caused the SAEs. 563 U.S. at 44-45. Nor does Plaintiffs' reliance on the "frequency of SAEs" get them over the pleading hurdle. (Opp. at 19.) The Opposition ignores both that the FDA considers numerous factors beyond the mere frequency of SAE reports in assessing whether a reliable causal link is established and that many PBC patients have liver comorbidities. Musoff Decl. Ex. 15 at 6-7, 18.) Plaintiffs' continued emphasis on the frequency of the SAEs (which here amounts to about only a 1% occurrence rate) confirms that Plaintiffs do not have enough under *Matrixx*.[3]

[3] Plaintiffs' cases do not help them. In *In re Acadia Pharms. Inc. Sec. Litig.*, 2020 WL 2838686, at *6 (S.D. Cal. June 1, 2020), the court found that the plaintiff had adequately pled that statements repeatedly touting the efficacy and safety of a newly-marketed drug were misleading where, as alleged in the complaint, the company failed to disclose hundreds of reports

3. *Plaintiffs Fail To Allege A Strong Inference Of Scienter Because Defendants Had No Duty To Disclose The NISS Investigation Earlier In Time.* In response to Defendants' argument that the NISS investigation was properly and timely disclosed in the risk factors section of the August 10, 2020 10-Q (Mov. Br. at 25-26), Plaintiffs argue that investors could not have discerned that the risk factors contained new information about the NISS investigation because the statements contained "no distinguishing features" and were located under one general risk factor heading spanning 54 pages. (Opp. at 17-18.) That is demonstrably false. The NISS investigation was disclosed under *two* separate and specific risk factors with specific headings and bolded subheadings that directly concerned risks related to "undesirable side effects" and potential "safety and labeling changes required by the FDA." (Musoff Decl. Ex. 8 at 47, 56, 63.) The disclosures spelled out in plain language the status of the investigation and advised investors that the FDA had not reached any conclusions about the potential safety risk.[4] (*Id.* at 57, 64.) Under these circumstances, Plaintiffs' conclusory assertion that the "market did not notice and digest" the NISS investigation (Opp. at 18) lacks any factual basis.[5]

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of deaths in patients taking the drug. In *Bartelt v. Affymax, Inc.*, 2014 WL 231551, at *12 (N.D. Cal. Jan. 21, 2014), the court reasoned that a reasonable investor would have found the undisclosed SAEs material in part because the company itself believed that the SAEs "warranted a total recall of its drug." And in *Silverstrand Invs. v. AMAG Pharms., Inc.*, 707 F.3d 95, 104-06 (1st Cir. 2013), allegations of undisclosed SAEs were sufficient to state a Section 11 claim because, among other things, (i) the FDA had initially declined to approve the company's drug due to a single case involving the same undisclosed SAE, (ii) no drug-related deaths had been found at the time of approval, and (iii) the occurrence rate of SAEs was more than two times higher than what was expected. No such similar circumstances are even remotely alleged here.

[4] Plaintiffs' only cited case is inapposite. *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 453 n.11 (S.D.N.Y. 2005) (information was disclosed in two non-consecutive footnotes using language that made it "virtually impossible to discern what exactly the company [was] alluding to").

[5] Because Defendants disclosed the NISS investigation long before the STAT news article repeated that same disclosure on October 8, 2020—without providing new information—the

Faced with these undisputed disclosures, Plaintiffs are left to argue that the NISS investigation should have been disclosed immediately, presumably on a Form 8-K. (Opp. at 12.) The Opposition does not (and cannot) contend that Defendants had any existing independent duty to disclose the pending NISS investigation. Plaintiffs instead argue that Defendants should have disclosed the NISS investigation immediately because it was a "material risk to the approval of the NASH NDA." (Opp. at 14-15.) As Defendants demonstrated, however, nowhere in the FAC do Plaintiffs allege any plausible or particularized facts connecting the NISS investigation in *PBC patients with cirrhosis* to the FDA's actions on the *noncirrhotic NASH NDA*.[6] (Mov. Br. at 23-25.) The Opposition confirms that Plaintiffs are asking this Court to draw inferences connecting these two unrelated events based on nothing more than conjecture.

First, Plaintiffs point to the May 22, 2020 press release announcing that the FDA had postponed the AdCom meeting so that it could review additional data concerning noncirrhotic NASH patients and argue that it is "reasonable to infer based on the timing of these events" that the NISS investigation could affect the approval of the NASH NDA. (Opp. at 12-13). Plaintiffs do not identify any confidential witness statement, internal document or FDA communication supporting this inference and instead double down on public news articles "theoriz[ing]" that the NISS investigation may have contributed to the FDA's decision on the NASH NDA. (Opp. at 13; FAC ¶¶ 71-72.) The news media's speculation about the FDA's decision-making is wholly insufficient to support a claim of securities fraud. (Mov. Br. at 25 (citing cases).) Plaintiffs' requested inference is also undermined by the FDA's own guidance demonstrating that, at the

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STAT news article is not "corrective" and the subsequent stock price drop does not support loss causation. (Opp. at 35; Mov. Br. at 35.)

[6] For the same reason, Plaintiffs' loss causation arguments based on stock price drops occurring after the May 22, 2020 and June 29, 2020 disclosures concerning the NASH NDA fail. (Opp. at 33-35; Mov. Br. at 34-35.)

time the NISS investigation was announced in May 2020, the FDA had not drawn any conclusions about a causal relationship between Ocaliva and the potential safety issue. (Mov. Br. at 21; Musoff. Decl. Ex. 19 at 8-9, 15.) Tellingly, the FDA also classified the NISS investigation in its *lowest* category of concern (a *potential* risk), permitting the FDA a year to investigate before making any conclusions about safety. (*Id.*)

Plaintiffs next point to the June 29, 2020 press release discussing the CRL and argue that the NISS investigation in PBC patients should have been disclosed immediately because it involved "the same drug (OCA) affecting the same organ (liver) via the same mechanism (FXR, a nuclear receptor that regulates bile acid synthesis and clearance from the liver)" as NASH. (Opp. at 13 (emphasis omitted).) Plaintiffs' argument relies on the unsupported inference that the FDA's statement that the predicted benefit of OCA for noncirrhotic NASH based on a surrogate endpoint "remains uncertain and does not sufficiently outweigh the potential risks" means that it is "beyond dispute that the FDA was concerned with the *full safety profile of OCA* when reviewing the NASH NDA." (Opp. at 9, 13 (emphasis added).) Yet in the very next sentence in the press release (which Plaintiffs ignore), Intercept disclosed that the FDA asked for additional efficacy and safety data from the ongoing ***noncirrhotic NASH*** trial, not safety data concerning Ocaliva's use in PBC patients. (Musoff Decl. Ex. 5.) Plaintiffs also argue that Defendants "make much ado of the fact that the NDA was for noncirrhotic NASH while the NISS investigation assessed PBC patients with cirrhosis." (Opp. at 13). Yet the FDA itself distinguishes between those two different patient populations when evaluating drug applications for NASH.[7] Plaintiffs' contention that the FDA would "undoubtedly" be concerned about safety

[7] *Compare* https://www.fda.gov/media/119044/download (guidance for noncirrhotic NASH) with https://www.fda.gov/media/127738/download (guidance for cirrhotic NASH).

risks observed in *cirrhotic* PBC patients when evaluating the *noncirrhotic* NASH NDA is simply unsupported. (Opp. at 13.) The Court need not resolve these issues, however, because Plaintiffs' disagreement about the proper interpretation or relevance of Ocaliva's safety data across the two distinct diseases and different disease stages does not support a claim for securities fraud. (Mov. Br. at 18 (citing cases).)[8]

Second, the Opposition argues that, because Intercept had warned investors that any "perceived" safety concerns with Ocaliva could jeopardize its NASH opportunity and the NISS investigation was material to the approval of the NASH NDA, it should have disclosed the NISS investigation immediately. (Opp. at 15.) But the FDA does not evaluate drug approvals based on what the market might perceive to be a safety risk (the FDA evaluates *real* data), and therefore any alleged perceived risks about Ocaliva's safety as a result of the NISS investigation could not have affected the NASH NDA approval (assuming it was relevant at all).

Third, to the extent that Plaintiffs are suggesting that the NISS investigation may have been "relevant or of interest to a reasonable investor," that circumstance alone does not mandate immediate disclosure. *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153 (2d Cir. 2013). In the context of a NISS investigation involving complex pharmacovigilance matters, Defendants were permitted to take time to understand the nature and scope of the *potential* safety signal and its potential implications before evaluating any disclosure obligations to the market (indeed, it was

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Intercept itself is separately studying OCA for patients with compensated cirrhosis due to NASH. *See* https://clinicaltrials.gov/ct2/show/NCT03439254?term=ocaliva&draw=3&rank=15.

[8] Plaintiffs contend that Intercept's Phase 1 studies of OCA show that Intercept considers the safety among PBC and NASH patients to be related. (Opp. at 21 n.14.) Not so. The Phase 1 trials generally studied the pharmacokinetics of OCA in small patient populations largely consisting of healthy volunteers who were exposed to OCA for just a few months. *See* https://clinicaltrials.gov/ct2/results?intr=INT+747&spons=intercept&age_v=&gndr=&type=&rslt=&phase=0&Search=Apply. By contrast, the Phase 3 studies separately evaluated OCA for a substantially longer period of time in patients who actually had PBC or NASH.

the reasonable and prudent thing to do). The Opposition largely ignores Defendants' authority on this point (*see* Mov. Br. at 20-22), and the one rebuttal attempt Plaintiffs do make falls flat.

Plaintiffs try to distinguish *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 198 (S.D.N.Y. 2008) on the basis that the company there needed time to evaluate the causal link between its drug and SAEs that participants experienced in a controlled clinical study, while here Intercept was already notified by the FDA about a possible safety signal and thus there was "no comparable inquiry for Defendants to make before their duty to disclose" arose. (Opp. at 16.) If anything, Defendants' need for time to evaluate the NISS was greater than the need recognized in *Elan* because the NISS was largely based on unverified SAE reports concerning patients who took Ocaliva in an uncontrolled postmarketing setting. (Mov. Br. at 21.) The NISS investigation was also in the evaluation phase and neither the FDA nor Intercept had made any conclusions about whether a causal link between Ocaliva and the potential safety risk existed. (*Id.*) Compared to Plaintiffs' unsupported inference that Defendants "intentionally delayed" disclosing the NISS investigation (Opp. at 26), the "much more reasonable inference" is that Defendants "used this time to investigate, to gather more information, and to confer with" the "FDA before taking any action." *Elan*, 543 F. Supp. 2d at 217; *Slayton v. Am. Express Co.*, 604 F.3d 758, 777 (2d Cir. 2010).[9]

Fourth, the Opposition asserts that Defendants made "numerous statements" between the time they learned about the NISS investigation in May 2020 and when it was disclosed on August 10, 2020 that demonstrate scienter. (Opp. at 26-27.) Yet Plaintiffs concede (as they

[9] Plaintiffs' contention that scienter can be inferred from Defendants' decision not to disclose the details of their *ongoing* dialogue with the FDA until after the NISS investigation was disclosed (Opp. at 17) ignores that there is "no legal obligation to loop the public into each detail of every communication with the FDA." *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017).

must) that those statements were made in the specific context of discussing the *noncirrhotic NASH NDA* and the observed safety issues of OCA in that specific patient population. (*Id*; Mov. Br. at 24.) The statements had nothing to do with any safety events observed in *cirrhotic* PBC patients with *cirrhosis*, and therefore the NISS investigation was never put "in play." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014).

4. *Plaintiffs' Additional Scienter Allegations, Individually Or Collectively, Add Nothing.*

First, Plaintiffs' conclusory allegations that Defendants were aware of the SAEs fail because, even if taken as true, Plaintiffs do not even attempt to allege that the knowledge of certain SAEs in PBC patients contradicted any challenged statement about the NASH NDA at the time it was made. Allegations that Defendants reviewed data and talked with the FDA (Opp. at 28)—without particularized allegations about what Defendants learned from those meetings—add nothing. ***Second***, relying solely on inapposite cases predating *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020), which held that naked assertions about a company's core product, standing alone, are not sufficient to support scienter, Plaintiffs argue just that: that scienter can be inferred because Ocaliva is Intercept's core product. (Opp. at 29.) That allegation is insufficient. ***Third***, Plaintiffs argue that the resignations of three executives were "highly unusual" given the timing of their departures soon after the NISS was disclosed. (Opp. at 30.) Plaintiffs ignore that the resignations occurred several months *after* the Class Period, and two of the three executives remained on as consultants (with Dr. Pruzanski staying on as a ***current director of the board***). (Mov. Br. at 28.) Plaintiffs' cases are thus inapposite.[10] ***Fourth***, Plaintiffs argue that the Court

[10] *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 381 (S.D.N.Y. 2007) (executives resigned immediately after alleged fraud was revealed); *In re Sadia, S.A. Sec. Litig.*, 643 F. Supp. 2d 521, 523-24 (S.D.N.Y. 2009) (CFO fired immediately and directors resigned ten days later); *Hall v. The Children's Place Retail Stores, Inc.*, 580 F. Supp. 2d 212, 232 (S.D.N.Y. 2008) (executive resigned after disclosure that he allegedly admitted to violating company policy).

should disregard that all of Dr. Pruzanski's challenged stock sales were made under a 10b5-1 trading plan because Defendants have not shown that the trading plan was entered into before the Class Period. (Opp. at 31.) Even assuming that to be true, Plaintiffs allege no facts supporting an inference that Dr. Pruzanski "strategically" used the plan to trade on inside information. *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 585 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015). The overall circumstances of Dr. Pruzanski's sales independently negate an inference of scienter. Dr. Pruzanski *increased* his holdings during the Class Period, and Plaintiffs' contention that he received those increased shares for free (Opp. at 32) is irrelevant. *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 763 (S.D.N.Y. 2018) (zero-cost shares count toward holdings analysis). Dr. Pruzanski also sold, at most, 10.7% of his shares (Opp. at 32), and courts routinely find similar percentages to be insufficient. (Mov. Br. at 9 (citing cases).)

CONCLUSION

The Opposition's one-line request at the end of the brief (Opp. at 35) seeking to file yet another amended complaint should be rejected and the FAC dismissed with prejudice. *Gregory v. ProNAi Therapeutics Inc.*, 757 F. App'x 35, 39 & n.6 (2d Cir. 2018) (leave to amend denied where request was made in opposition brief but included no proposed changes (as here)).

Dated: New York, New York
June 9, 2021

Respectfully submitted,

/s/ Scott D. Musoff

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